PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 21429WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/NL 03/00881	International filing date *(day/month/year)* 11.12.2003	Priority date *(day/month/year)* 11.12.2002
International Patent Classification (IPC) or both national classification and IPC A61L31/04		
Applicant DSM IP ASSETS B.V. et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21.06.2004	07.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Menidjel, R Telephone No. +31 70 340-3680

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/NL 03/00881

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-6 as originally filed

Claims, Numbers

1-9 received on 11.11.2004 with letter of 09.11.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-9
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 - The following documents (D1,D2,D3,D4) are referred to in this communication (Article 33(6) PCT); the numbering will be adhered to in the rest of the procedure:

D1: US-A-3 124 136 (FRANCIS C. USHER) 10 March 1964 (1964-03-10)

D2: EP-A-0 561 108 (UNITED STATES SURGICAL CORP) 22 September 1993 (1993-09-22)

D3: US-A-3 054 406 (USHER FRANCIS C) 18 September 1962 (1962-09-18)

D4: EP-A-0 205 960 (ALLIED CORP) 30 December 1986 (1986-12-30)

- The amendments filed by the applicant do not introduce subject-matter which extends beyond the content of the application as filed (Article 34(2)(b) PCT).

2. Novelty (Article 33(2) PCT)

- The subject-matter of present claims 1-9 is considered as novel over the cited prior art for the following reasons (Article 33(2) PCT):

- Documents D1 (US3124136) describes a woven surgical mesh and method to obtain it, wherein the woven surgical mesh is made of polyethylene thread or yarn having a tensile strength in the range of 50,000-150,000 p.s.i. (0.3-1.0 GPa). The polyethylene mesh described in document D1 is inert and nonirritating even in the presence of infection (Cf. D1, column 1, lines 22-63; column 2, line 39-column 3, line 59; column 4, lines 26-60; column 5, lines 6-38).

Document D1 does not refer to polyethylene yarns having a tensile strength of more than 1.0 GPa nor a sheath which is a substantially non-porous layer.

Document D2 (EP0561108) discloses a surgical repair suture product and method to obtain it, wherein the textile surgical articles are constructed in whole or in part from high tenacity low elongation fibres such as ultra-high molecular weight extended chain polyethylene high tenacity fibers. The fibres exhibit strengths from 375-560 kpsi (2.25-3.36 GPa) and tensile moduli of from 15-30 msi (Cf. D2, page 2, line 55-page 3, line 7; page 3, lines 41-53; page 4, line 19-page 5, line 11; claims 1-14).

Document D2 does not refer to surgical mesh nor to a sheath which is a substantially non-porous layer.

- Document D3 (US3054406), cited by the Applicant, describes surgical mesh and method

to obtain it, wherein the surgical mesh is made of polyethylene thread or yarn having a tensile strength in the range of 50,000-150,000 p.s.i. (0.3-1.0 GPa). The polyethylene used to prepare the mesh is known in the art as "high-density" or "low-pressure" polyethylene (Cf. D3, column 1, lines 8-30; column 1, lines 46-53; column 1, line 72-column 2, line 60; column 3, lines 29-61; claims 1-5).
Document D3 does not refer to polyethylene yarns having a tensile strength of more than 1.0 GPa nor a sheath which is a substantially non-porous layer.

- Document D4 (EP0205960), cited by the Applicant, discloses very low creep, ultra high modulus, low shrink, high tenacity polyethylene fibre having good strength retention at high temperatures and the method to produce such fibre. The fibre described in document D4 has a tenacity of at least about 1.73-2.77 GPa and are used as implants, sutures and prosthetic devices (Cf. D4, column 1, lines 29-44, column 2, line 39-column 3, line 26; column 3, line 34-column 4, line 5; examples 1-13).
Document D4 does not describe a surgical mesh nor yarns with a substantially non-porous sheath layer around a filamentous core.

3. Inventive Step (Article 33(1),(3) PCT)
- The subject-matter of present claims 1-9 does involve an inventive step for the following reasons (Article 33(1),(3) PCT):

- The subjective problem to be solved by the present application is to provide a surgical soft tissue mesh, which combines flexibility with a high tenacity to obtain a thinner mesh that allows the mesh to be rolled or folded and thereafter inserted into the cannula of a needle for deployment in the body.

- The solution proposed in the present application is a soft and flexible surgical tissue mesh comprising polyethylene yarns as described in present claim 1.

- Document D3 (US3054406), cited by the Applicant, describes surgical mesh and method to obtain it, wherein the surgical mesh is made of polyethylene thread or yarn having a tensile strength in the range of 50,000-150,000 p.s.i. (0.3-1.0 GPa). The polyethylene used to prepare the mesh is known in the art as "high-density" or "low-pressure" polyethylene (Cf. D3, column 1, lines 8-30; column 1, lines 46-53; column 1, line 72-column 2, line 60; column 3, lines 29-61; claims 1-5).

- The difference between the teaching of the closest prior art and the present invention is that the polyethylene yarns have a tensile strength of more than 1.0 GPa with a

substantially non-porous sheath layer around a filamentous core.

- The technical effect of this difference is the provision of a soft and flexible surgical soft tissue mesh which combines flexibility with sufficient tenacity.

- Hence, the subject-matter of present claims 1-9 would not have been an obvious option for the skilled person, and therefore present claims 1-9 involve an inventive step (Article 33(1),(3) PCT).

4. Industrial Application (Article 33(4) PCT)

- The subject-matter of present claims 1-9 is considered to be industrially applicable; claims 1-9 therefore, satisfy the criterion set forth in Article 33(4) PCT.

Enclosures to letter dated 09 November 2004 concerning European Patent Appln. No. PCT/NL2003/000881; -DSM IP Assets B.V.-; ref: 21429WO.

AMENDED SET OF CLAIMS

1. Soft and flexible surgical soft tissue mesh comprising polyethylene yarns, characterized in that the polyethylene yarns have a tensile strength of more than 1.0 GPa, determined as specified in ASTM D885M using a nominal gauge length of the fibre of 500 mm and a crosshead speed of 50%/min, consist of polyethylene with a relative viscosity of more than 5 dl/g as measured on a solution of polyethylene in decalin with a concentration of 0.05% at 135°C according to ASTM D 4020, and are sheath and core yarns having a weight ratio between the sheath and the core of below 5:1, wherein the core is formed by filaments that show no or only little adhesion to each other and the sheath is a substantially non-porous layer.
2. Mesh according to claim 1, wherein the mesh is knitted.
3. Mesh according to claim 1 or claim 2, wherein the yarns have a weight ratio between the sheath and the core of below 3:1.
4. Mesh according to any of claims 1-3, wherein the yarn comprises a medical drug.
5. Method of producing a soft and flexible surgical soft tissue mesh comprising polyethylene yarns, characterized in that yarns are applied that comprise filaments made by:
   a) spinning at least one filament from a solution of polyethylene with a relative viscosity of more than 5 dl/g, as measured on a solution of polyethylene in decalin with a concentration of 0.05% at 135°C according to ASTM D 4020, in a first solvent;
   b) cooling the filament obtained to form a solvent-containing gel filament;
   c) removing at least partly the solvent from the gel filament; and
   d) drawing the filament in at least one drawing step before, during or after removing solvent, to result in a tensile strength of more than 1.0 GPa, determined as specified in ASTM D885M using a nominal gauge length of the fibre of 500 mm and a crosshead speed of 50%/min;
   further comprising a step wherein the yarns are subjected to a heat treatment to form a modified yarn comprising a sheath and a core with a weight ratio between sheath and core of below 5:1, which sheath is substantially non-porous.
6. Method according to claim 5, wherein the weight ratio is below 3:1.
7. Method according to claim 5 or 6, wherein the heat treatment is performed in the presence of a second solvent for polyethylene.
8. Method according to any one claims 5-7, further comprising a step of incorporating a medical drug into the yarns by adding the drug to the first or the second solvent.
9. Method according to any one of claims 5-8, further comprising a step of heating the mesh under constant strain at a temperature between the melting temperature of the polyethylene and a temperature not more than 20 degrees below the melting temperature.